

REMARKS

Claims 14 – 18 and 29 are pending.

As an initial matter, Applicants acknowledge with thanks the Examiner's withdrawal of an obviousness rejection of claims 14 – 18 and 29, advanced in an office action dated January 14, 2003.

On page 3 of the Office Action, the Examiner has rejected claims 14 – 15, 18 and 29 under 35 U.S.C. § 103(a) as being unpatentable over McCoy in view of Loer. Applicants respectfully traverse this rejection.

In this context, the Examiner must present evidence of both (a) some suggestion or motivation to modify the reference or to combine prior-art teachings and (b) a reasonable expectation of success in such a modification or combination. In addition, the reference or references must teach or suggest each feature recited in the claim under consideration.

McCoy teaches fusion proteins comprising thioredoxin linked to a heterologous protein or peptide. The purpose of preparing the fusion proteins in McCoy is to increase the production and activity and improve the stability or solubility of the heterologous proteins. In one embodiment, the protein fusions are prepared in the cytoplasm and released from the cell by applying osmotic shock or applying freeze/thaw treatments to the cell. In another embodiment, the fusion proteins are prepared as soluble proteins which are secreted into the periplasmic space or culture medium.

McCoy does not evidence motivation in the art to have prepared either thioredoxin on oil bodies or an emulsion formulation that contains thioredoxin, as recited in the claims. More specifically, the present claims are directed to the preparation of emulsion formulations that contain a fusion protein comprised of (i) thioredoxin or thioredoxin reductase and (ii) a portion of an oil body protein sufficient to target the fusion protein to oil bodies in a cell. Pursuant to the claimed invention, oil bodies containing the fusion protein subsequently are isolated from the cell, washed, and formulated into an emulsion.

McCoy is not concerned with the preparation of thioredoxin-containing emulsion formulations *per se* but rather with the use of thioredoxin to stabilize the production of other heterologous proteins. Accordingly, McCoy says nothing that implicates preparing thioredoxin as an emulsion with oil bodies.

The deficiencies in McCoy are not remedied by Loer. Loer merely teaches a methodology for isolating oil bodies from soybean seeds.¹ Loer does not disclose or suggest the preparation of thioredoxin containing emulsions.

It is apparent, therefore, that the Examiner has not marshaled evidence of a suggestion or motivation in the prior art to have modified McCoy or have combined its teachings with those of Loer, thereby to arrive at the claimed invention.² The Examiner also has failed to identify evidence that would have supported a reasonable expectation of success to those ends. Lastly, the combination of McCoy and Loer do not teach all of the claim recitations. Since McCoy in view of Loer therefore does not render claims 14 – 15, 18 and 29 unpatentable under § 103(a), reconsideration and withdrawal of the rejection are requested.

On page 4 of the Office Action, the Examiner has rejected claims 16 and 17 under §103(a) over McCoy in view of Loer “as applied to claims 14 – 15, 18 and 29,” and further in view of Hildebrand. Applicants respectfully traverse this rejection.

Claims 16 – 17 concern embodiments of the invention in which the fusion proteins are prepared in a plant (claim 16), such as a safflower plant (claim 17). Applicants already have

¹ The Examiner also points out that, in “the state of the art, methods of preparing products by forming emulsions are well known and practiced in the art. For example, U.S. Patent No. 5,683,740 (form PTO-1449) teach how to prepare oil bodies by washing and forming emulsions and ultimately concentrating the emulsion (Column 2). Applicants respectfully disagree with this statement, since the '740 patent teaches lipidic vesicles and not oil bodies. The specification of the '740 patent states that a process is applied in which 70 – 90% of the oil is removed. *See* column 1, lines 32-37. If oil bodies were to be isolated using the methodology of the '740 patent, the oil bodies would be substantially destroyed. Destruction of the oil bodies does not occur during the process of the present invention.

² On page 4 of the Office Action, the Examiner contends that one of ordinary skill would have been motivated to prepare an emulsion as claimed because “making such fusion protein...increase[s] the efficiency of the production of the protein.” Applicants, however, are not interested in and are not claiming a method for “increas[ing] the efficiency of the production of the [heterologous] protein,” an oil body protein in this case. Instead, Applicants’ claims are directed to a method for producing an emulsion comprising thioredoxin or thioredoxin reductase prepared on an oil body protein. There is no motivation evidenced in the art to have prepared a thioredoxin-containing emulsion formulations according to the claimed method.

elaborated on the reasons why McCoy/Loer does not render the claims obvious. The deficiencies of the combination -- neither McCoy nor Loer suggests the production of thioredoxin fusion proteins in plants -- are not remedied by Hildebrand.

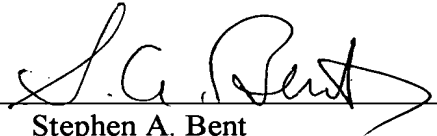
Hildebrand teaches expression cassettes for the genetic modification of plants, to increase their production and content of unsaturated fatty acids and corresponding lipids. Hildebrand also teaches that safflower plants may be transformed, using such cassettes. Applicants submit, however, that no reasonable combination of the cited references could have suggested preparing thioredoxin-containing emulsions in plants, let alone in safflower plants. Reconsideration and withdrawal of the rejection therefore are respectfully requested.

Applicants believe that the application now is in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned, should he feel that any other issue requires consideration.

Respectfully submitted,

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